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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,026

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Stephen Solomon

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08/17/2006

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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/764,026

Applicant(s)

SOLOMON, STEPHEN

Examiner

Ellsworth Weatherby

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/23/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. Regarding the drawings, Figure 5 and Figure 6 are illegible and irreproducible; therefore they do not contain any patentable substance. It is suggested that these figures be removed from the application or resubmitted in higher quality.

### ***Claim Objections***

2. Claims 10 and 11 are objected to because of the following informalities: They repeat claims 7 and 8. Appropriate correction is required for consideration.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Vesely et al. (USPN 6,019,725).

Regarding claims 1-9, Vesely et al. '725 teaches a three-dimensional tracking and imaging system comprising a sensor and an imaging device that is synchronized with a real-time electrocardiogram. Furthermore, the position of the sensor is registered to known anatomic landmarks and the moving image by touching the sensor to the landmarks and indicating the position of the landmarks on the image. The sensor position data is then superimposed on the electrocardiogram-synchronized moving image. Vesely et al. '725 discloses:

A 3-D tracking and imaging system for tracking the position of a surgical instrument (e.g., a catheter, probe, a sensor, needle or the like) inserted into a body, and displaying a 3-D image showing the position of the surgical instrument in reference to a 3-D image of the environment surrounding the surgical instrument (abstract).

The 3-D tracking registers the position of a sensor inserted in the heart by touching the sensor to the wall of the beating heart and matching the defined beating structure with the moving image of the beating heart. Vesely et al. '725 discloses:

Imaging modality system 1624 acquires 2-D, 3-D or 4-D image data sets from an imaging source, such as fluoroscopy, an MRI (magnetic resonance imaging), CT (computerized tomography) or 2-D or 3-D ultrasound device, to provide a "template" through or against which the shape, position and movement of instrument 1670 being tracked can be displayed. The template typically takes the form of an image of the environment surrounding the instrument (e.g., a bodily structure). It should be noted that if multiple (3-D) volumes are acquired at different time intervals, a 4-D image is obtained (i.e., 3-D image changing over time) (col.13, lines 39-50).

In a similar manner, the transducers mounted to the instrument can be located in such a way as to build up a 3-D surface patch image of a bodily structure, such as an organ. For example, transducers mounted to a catheter can be located in such a way as to build up a 3-D surface patch image of the inside of a beating ventricle, by simply dragging the catheter along the wall of the ventricle in the area of interest (col. 15, lines 26-33).

One of the most critical aspects of the 3-D scene relationship and evaluation module is the placement of the 3-D image of the instrument in the correct spatial relationship with the underlying images showing the environment surrounding the instrument. This is done by registering features in the images, such as the reference transducers, with their position in the measuring coordinate system. This process uses standard coordinate transformation operations, and only requires for input information as to which feature in the image space corresponds to the same feature (i.e., transducer) in the measurement space (col. 16, lines 16-26).

Vesely et al. '725 also teaches synchronizing prerecorded diagnostic images with an electrocardiogram to produce a moving image that is continuously matched with the patient heart rate. Vesely et al. '725 discloses:

For moving image sets, such as 2-D video loops, or 3-D ultrasound loops of the heart, the motion of the image data sets need to be output at a rate that continually matches that of the patient heart beat. If the image data set that is played back is not synchronized with the current state of the heart, then the 3-D scene will not be

displayed in a recognizable format and abnormal motion of the catheters relative to the images, will result (col. 16, lines 36-44).

The first step in synchronizing "video loops" with a patient's heartbeat is to input a raw ECG signal into the processing computer (module 1128). The ECG signal is converted into digital data using a standard A/D converter (module 1130). The digital data is then fed into sync generator module 1124, which includes an algorithm that produces a timing signal that corresponds to the current activity of the heart (col. 16, lines 45-52).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2,3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesely et al. '725 in view of Ben-Haim et al. (USPN 5,443,489).

Vesely et al. '725 teaches using previously acquired two dimensional or three dimensional image data sets that are continuously synchronized with an electrocardiogram taken during a medical procedure to produce moving images that correspond to the current phase and state of the heart (col. 16, lines 36-44). Vesely et

al. '725 also discloses registering the positional data of a medical catheter on the moving image (col. 16, lines 16-26). Vesely et al. '725 also teaches collecting positional coordinates of the sensor with each beat to define a beating structure (col.13, lines 39-50). Vesely et al. '725 also teaches having inputs for electrical and pressure measurements within the beating heart (col. 9, lines 31-42).

Vesely et al. '725 does not expressly teach using electrical potentials or pressure measurements as landmarks for defining the interior of a beating heart.

Ben-Haim et al. '489 teaches a trackable mapping/ablation system having a catheter with a transmitting or receiving antenna for the relevant field within its tip, a sensor at its tip for acquiring local information such as electrical potentials, chemical concentration, temperature, and/or pressure to interrogate and transmit the chamber boundary information to an image processor for superposition on a perspective image (col. 3, lines 44-62).

It would have been obvious to combine the three-dimensional tracking and imaging system comprising a sensor and an imaging device that is synchronized with a real-time electrocardiogram as taught by Vesely et al. '725 with the trackable catheter having sensors for pressure and electrical potentials taught by Ben-Haim et al. '489. The motivation to combine the two would have been to better correlate known anatomic positions on the moving image with the local information recorded by the catheter sensors resulting in a more precise tracking system.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EW

  
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